ISRCTN12604075 https://doi.org/10.1186/ISRCTN12604075

# Safety trial of a locally-developed trunk and lower limb rehabilitation robot

**Submission date**
17/01/2025

**Recruitment status**
No longer recruiting

**Registration date**
24/01/2025

**Overall study status**
Completed

**Last Edited**
23/01/2025

**Condition category**
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

**Plain English summary of protocol**

Background and study aims
The TAYO project aims to improve physical therapy care using a device called the Lower Limb Mobilization (LLMo). This device helps physical therapists perform passive range of motion exercises for people in the early stages of recovery after a stroke.

Who can participate?
Healthy individuals aged 18 to 65 years old.

What does the study involve?
Participants will perform range of motion exercises using the LLMo device. During the trial, their vital signs, comfort, and pain levels will be continuously monitored to ensure the device's safety.

What are the possible benefits and risks of participating?
Participants may feel some stretching in their lower extremities. Although the device is external and does not exchange energy with the patient, there is a risk associated with the device moving the participants' limbs. The device has passed rigorous mechanical and electrical tests to ensure safety.

Where is the study run from?
The study is conducted at the De La Salle University - Laguna Campus research lab (Philippines)

When is the study starting and how long is it expected to run for?
March 2023 to June 2023

Who is funding the study?
The study is funded by the Department of Science and Technology - Philippine Council for Health Research and Development (DOST-PCHRD)

Who is the main contact?
Engr. Julius Banayo, julius.banayo@dlsu.edu.ph

## Contact information

### Type(s)
Principal investigator


### Contact name
Dr Armyn Sy

### ORCID ID
https://orcid.org/0009-0005-4838-2735

### Contact details
2401 Taft Ave.
Manila
Philippines
922
+63 9177748816
armyn.sy@dlsu.edu.ph


### Type(s)
Public, Scientific


### Contact name
Mr Julius Banayo

### Contact details
727V+352, LTI Spine Road, Laguna Blvd
Biñan, Laguna
Philippines
4024
+63 9162870211
julius.banayo@dlsu.edu.ph


## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
AHMC 2023-01

## Study information

### Scientific Title
A pilot study among normal subjects on the safety and functionality of a locally-developed trunk and lower limb rehabilitation robot

### Study objectives

The lower limb rehabilitation robot is safe to use among healthy participants

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 23/03/2023, Asian Hospital and Medical Center Research Ethics Committee (2205 Civic Dr, Muntinlupa, Metro Manila, 1780, Philippines; +63 (02) 8771 9000; info@asianhospital.com), ref: AHMC 2023-01

## Study design
Interventional non-randomized

## Primary study design
Interventional

## Study type(s)
Safety

## Health condition(s) or problem(s) studied
Passive range of motion among healthy adult participants

## Interventions
After meeting the inclusion criteria and medical evaluation, participants' vital signs (blood pressure, heart rate, and oxygen saturation) and lower limb measurements were recorded prior to the trial. They were then secured to the Lower Limb Mobilization (LLMo) device and performed three repetitions of each prescribed lower limb exercise. Lower limb angles were measured after each repetition. Throughout the exercises, the attending physiatrist and physiotherapist consistently monitored the participants, sought feedback and pain assessments from participants. Following the exercises, participants' vital signs were recorded before, during and at end of exercise. Additionally, they were given a survey to assess their perceptions of the LLMo's safety, feasibility, and acceptability while performing exercises.

## Intervention Type
Device

## Phase
Phase 0

## Drug/device/biological/vaccine name(s)
Lower Limb Mobilization Device (LLMo Device)

## Primary outcome(s)
Safety evaluation:
1. Safety checklist used to inspect device before the trial
2. Pain assessment administered as needed during the exercises
3. Adverse events reported as needed throughout the entire trials

## Key secondary outcome(s))
1. Range of Motion of each exercise measured using goniometer at the end of each movement
2. Range of Motion of each exercise measured using device software at the end of each

movement
3. Patient perception of safety, feasibility, and acceptability measured using a survey at the end of each session
4. Comments regarding comfort recorded verbally over the course of the whole exercise session; Physiatrist wrote down notes comments in participant chart

### Completion date
17/06/2023

## Eligibility

### Key inclusion criteria
1. Be able to follow instructions
2. Be at least 5'4" (1.63 m) to 6'2" (1.87 m)
3. Weigh less than 200 kg
4. Have full use of their trunk and lower extremities
5. Agree to have medical clearance sponsored by the research prior to participation (validity: 1-2 weeks from appointed clinical study participation)
6. Be fully vaccinated against COVID-19 (2 completed doses, with or without boosters)

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
65 years

### Sex
All

### Total final enrolment
18

### Key exclusion criteria
With any known disabilities or comorbidities

### Date of first enrolment
01/05/2023

### Date of final enrolment
26/05/2023

# Locations

**Countries of recruitment**
Philippines

**Study participating centre**
**De La Salle University - Laguna Campus**
727V+352, LTI Spine Road, Laguna Blvd
Biñan, Laguna
Philippines
4024

# Sponsor information

**Organisation**
DLSU - Evelyn D. Ang - Institute of Biomedical Engineering and Health Technology

# Funder(s)

**Funder type**
Government

**Funder Name**
Department of Science and Technology, Republic of the Philippines

**Alternative Name(s)**
Republic of the Philippines, Department of Science and Technology, Department of Science and Technology, Philippines Department of Science and Technology, Department of Science and Technology, Philippines, Kagawaran ng Agham at Teknolohiya, DOST

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Philippines

# Results and Publications

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet version 2 | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | 10/02/2023 | 23/01/2025 | No | No |